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Docket No: «IMPORT_CASE/CPI_DOCKET_NO»
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In re application of: ZUQIN LAI et al)
Application No.: 10/599,758)
Filed: October 6, 2006)
For: PHARMACEUTICS OF TRADITIONAL)
CHINESE MEDICINE OF TREATING AIDS)

DECLARATION OF ZUQIN LAI AND XUHUI HUANG

We, Zuqin Lai and Xuhui Huang, hereby declare that:

1. We are the co-inventors of the above-identified patent application.
2. The Chinese medicine prescription of the present invention is originated from the clinical summary, and the prescription has been approved by China State Food & Drug Administration. The clinical trial has been conducted from October, 2002 to June, 2003. The trial is conducted completely according to the specifications in GCP (Good Clinical Practice) in five clinical bases, including Beijing You'an Hospital, Beijing Ditan Hospital, Peking Union Medical College Hospital, 302 Hospital of PLA and Kunming Third People's Hospital, and the trial results all indicate that this prescription can be used to treat AIDS, and various AIDS symptoms can be alleviated, such as alopecia, fatigue, emaciation and diarrhea, etc. In a treatment course of 6 months, CD4 count is increased by more than 30% in 50.57% patients. The drug prepared based on this prescription has obtained new drug license issued by China State Food & Drug Administration. Therefore, this invention is based on clinical practice, not a product of pure laboratory experiments, or deduced from theory. Case histories of some patients during the clinical trial are shown in Appendix 1.
3. We declare that all the statements made herein of own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. 1001) and may jeopardize the validity of the application and any patent issued thereon.

Date: Dec. 19, 2007

Zuqin Lai
Name: Zuqin Lai

Date: Dec. 19, 2007

Xuhui Huang
Name: Xuhui Huang

Application No. 10/599,758

APENDIX 1: Clinical Trial Results

Prescription

The weight portions of raw materials of "Tangcao Tablet" used in the clinical trial are as follows:

Geranium 120g, Honeysuckle Flower 120g, Pericarpium Trichosanthis 40g, Root of Chinese Thorowax 80g, Herb of Chinese Mosla 60g, Pomegranate Rind 60g, Root of Membranous Milkvetch 120g, Liquorice Root 80g, Flower of Common Bombax 80g, Stem of Suberect Spatholobus 120g, Safflower 60g, Radix Oryzae 200g, Fruit of Belleric Terminalia 40g, Herba Hedyotis Diffusae 120g, Fructus Trapae 120g, Ginkgo leaf 40g, Purslane herb 60g, Rhizoma picrorhizae 40g, Herba Solani Nigri 120g, and Scorpion 28g.

Note: Weight portions of raw material in the prescription can refer to "Standards of China State Food & Drug Administration (on trial), the standard code YBZ02562004". The above raw material was prepared into 1000 tablets according to the present invention, with each tablet weighing 0.4g. Oral administration: three doses daily, 8 tablets per dose.

Cases:

Example 1: Ms. Zhu, 47 years old, the random enrollment number was 182. Positive HIV was detected in 2001, and she was enrolled in this HIV/AIDS clinical trial when she went to visit doctors on Nov.18th, 2002.

- ☐ CD4 count was 178/mm³ before treatment, and was increased to 247/mm³ after 6 months of treatment, which was increased by 38%.
- ☐ Virus load was 243271 copy/ml before treatment, and was decreased to 33777 copies/ml after 6 months of treatment, which was decreased by 0.85747 Log.
- ☐ Clinical symptoms before treatment: Continuous loose stool, with food in stomach not digested, 3-5 times daily for more than 1 month, with normal appetite, low spirit, general fatigue, but can persist the daily work, with a few hairs left on the pillow after sleeping; normal functional grade.

Clinical symptoms after treatment: Diarrhea and fatigue were cured; poor appetite became normal; with a few hairs left on the pillow after sleeping; with normal functional grade.

Example 2: Mr. Wang, 37 years old, the random enrollment number was 037. Positive HIV was found in 2002, and he was enrolled in this HIV/AIDS clinical trial when he went to visit doctors on Nov. 18th, 2002.

- ☐ CD4 count was 274/ mm³ before treatment, and was increased to 358/mm³ after 6 months of treatment, which was increased by 30.7%.
- ☐ Virus load was 9038 copies/ml before treatment, and was decreased to 1541 copies/ml after 6 months of treatment, which was decreased by 0.76827 Log.
- ☐ Clinical symptoms before treatment: Frequent diarrhea, soft or loose stool 2-4 times daily for less than 1 month, poor appetite, and the appetite was decreased by 1/3, low spirit, but physical labor could be also executed, with no alopecia, normal functional grade. After treatment, diarrhea, poor appetite and fatigue were all became normal, with alopecia of light grade, normal functional grade.

Example 3: Ms. Qiao, 26 years old, the random enrollment number was 084. Positive HIV was found in 2002, and she was enrolled in this HIV/AIDS clinical trial when she went to visit doctors on Nov. 18th, 2002.

- ☐ CD4 count was 399/ mm³ before treatment, and was increased to 520/mm³ after 6 months of treatment, which was increased by 30.3%.
- ☐ Virus load was 4242 copies/ml before treatment, and was decreased to 1353 copies/ml after 6 months of treatment, which was decreased by 0.49627 Log.
- ☐ Clinical symptoms before treatment: Frequent diarrhea, soft or loose stool 2-4 times daily for less than 1 month, poor appetite, and the appetite was decreased by 1/3, low spirit, general fatigue, but daily work could be accomplished, alopecia of light degree, normal functional grade. After treatment, diarrhea, poor appetite and fatigue were all became normal, with alopecia of light grade, functional grade diagnosis was normal, with symptoms.

These symptoms became normal after treatment.

Example 4: Mr. Ren, 32 years old, the random enrollment number was 141. Positive HIV was found in Jan. 2002, and he was enrolled in this HIV/AIDS clinical trial when he went to visit doctors on Nov. 25th, 2002.

- ☐ CD4 count was 243/ mm³ before treatment, and was increased to 326/mm³ after 6 months of treatment, which was increased by 34.2%.

- ☐ Virus load was 101042 copies/ml before treatment, and was increased to 33345 copies/ml after 6 months of treatment, which was decreased by 0.48147 Log.
- ☐ Clinical symptoms before treatment: Frequent diarrhea, soft or loose stool 2-4 times daily for less than 1 month, poor appetite, and the appetite was decreased by 1/3, low spirit, but physical labor could be also executed, with a few hairs left over on pillow after sleeping, with normal functional grade.

After treatment, diarrhea, poor appetite and fatigue were all became normal, with alopecia of light grade and normal functional grade.